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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/523,033	03/10/2000	DEBORAH Y KWOH	P-IM-4082	4757

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EXAMINER

NAVARRO, ALBERT MARK

ART UNIT	PAPER NUMBER
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1645

DATE MAILED: 05/27/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/523,033

Applicant(s)

KWOH ET AL.

Examiner

Mark Navarro

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1,2 and 5-13 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,2 and 5-13 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 2/11/03.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_.

## **DETAILED ACTION**

### ***Claim Objections***

1. Claim 8 is objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim does not refer back in the alternative only. See MPEP § 608.01(n). Accordingly, the claim 8 has not been further treated on the merits.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1-2, 5, 9, 11 and 13 are rejected under 35 U.S.C. 102(b) as being anticipated by Swenson et al.

The claims are directed to a method of inducing an immune response that increases HDL cholesterol levels in a mammal exhibiting or at risk of exhibiting low levels of serum HDL cholesterol comprising administering to said mammal an immunogenic composition comprising a full length cholesteryl ester transfer protein (CTEP).

Swenson et al (Journal of Biological Chemistry Vol. 284, No. 24, pp 14318-14326, August 25, 1989) disclose of immunizing mice with purified CETP. (See page

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14319). Furthermore, Swenson set forth that CETP plays a role in the regulation of HDL-cholesteryl ester levels in rabbits and humans. (See page 14318).

Given that Swenson et al disclose of immunizing a mammal with full length CETP, and obtaining an antibody which was elicited against the CETP immunogenic composition, the disclosure of Swenson et al is deemed to anticipate the claimed invention. Furthermore, since Swenson et al administered human CETP as the immunogenic composition it is deemed to inherently comprise the sequence recited as SEQ ID NO: 1 of the instantly claimed invention, since it too is a human CETP sequence.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

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consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

3. Claims 1-2, 5-7, and 9-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Swenson et al in view of Nagashima et al and Maciak et al.

The claims are directed to a method of inducing an immune response that increases HDL cholesterol levels in a mammal exhibiting or at risk of exhibiting low levels of serum HDL cholesterol comprising administering to said mammal an immunogenic composition comprising a full length cholesteryl ester transfer protein (CTEP), wherein the composition comprises a carrier, and wherein the full length CETP is a rabbit CETP.

The teachings of Swenson et al are set forth above.

Swenson et al do not teach of compositions comprising a carrier, and wherein the full length CETP is a rabbit CETP.

Nagashima et al (Journal of Lipid Research Vol. 29 (12) pp 1643-1649, December 1988) teach of the sequence of rabbit CETP and its overall sequence homology of 81% compared to human CTEP, with two thirds of the amino acid substitutions being conservative. Nagashima et al further teach of extensive structural similarity between rabbit and human CETP. (See abstract).

Maciak et al (US Patent Number 5,264,341) teach that at the time of the invention it was well known that carriers, such as KLH, could be conjugated to a non-immunogenic molecule to render the molecule immunogenic. (See column 7).

Given that 1) Swenson et al teach of administering to mammals a full length human CETP protein and eliciting an immune response, and that 2) Nagashima et al teach of the extensive structural similarity between rabbit and human CETP, and that 3) Maciak et al teach of carriers, such as KLH, for rendering non-immunogenic molecules immunogenic, it would have been prima facie obvious to one of ordinary skill in the art at the time of the invention to have incorporated the rabbit CETP molecule as taught by Nagashima et al in the method taught by Swenson et al. It would have been further obvious to conjugate the protein to a carrier as taught by Maciak et al, since it was well known that conjugating non-immunogenic proteins to KLH would result in the ability to generate a response against a normally non-immunogenic molecule. One would have been motivated to produce such a method based upon the teaching by Nagashima et al that human CETP and rabbit CETP have "extensive structural similarity" and that CETP enhances the transfer of cholesteryl esters, triglycerides and phospholipids between lipoproteins as taught by Swenson et al.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark Navarro whose telephone number is (571) 272-0861.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on (571) 272-0864. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Mark Navarro  
Primary Examiner  
May 23, 2005